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INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			LIU, SAMUEL W	
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Art Unit: 1653



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 20040412

Application Number: 09/838044  
Filing Date: April 18, 2001  
Appellant(s): KASER ET AL.

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David G. Streeter  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed January 21 2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

No amendment after final has been filed.

**(5) *Summary of Invention***

The summary of invention contained in the brief is accurate.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that the claims stand or fall together for issues 1-3.

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior art of record***

Miller, E. J. et al. *Am. J. Physiol.* (1991) 260, 1-12.

Shafat, A. et al. (2000) *Mol. Pharmacol.* 58, 515-525.

**(10) *Grounds of Rejection***

The following grounds of rejection are applicable to the appealed claims:

**Utility/35 U.S.C. § 101**

Claims 15-16 and 19 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well-established utility.

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The instant application has provided a description of an isolated DNA encoding a polypeptide. The instant application does not disclose the biological or biochemical role of the polypeptide of SEQ ID NO:6 or its significance. Indeed, contrary to claim 15 recitation “substantially purified protein”, the claimed protein has not been shown to have been expressed in a cell and purified (i.e., not in hand). The instant specification asserts that the claimed polypeptide of SEQ ID NO:6 and immunogenic fragment thereof have utilities:

- The protein can be used to screen a library of molecules or compounds to identify at least one ligand which specifically binds the protein (see page 4, the 3<sup>rd</sup> paragraph).
- The protein can be used to purify a ligand from a sample (see page 4, the 3<sup>rd</sup> paragraph).
- The protein can be used to treat or to prevent a disease associated with the altered expression of a gene that is expressed in response to PAH in a subject in need” ; the said treatment or prevention “comprises administering to the subject in need the pharmaceutical composition containing the polypeptide in an amount effective for treating or preventing the disease” (see page 4, the 3<sup>rd</sup> paragraph).
- The disclosed polypeptide can be used for “the diagnosis of diseases characterized by the over-or-under expression of the disclosed protein” (see page 15, the last paragraph).
- The disclosed polypeptide can be used for drug screening assays in which neutralizing antibodies capable of binding the disclosed protein specifically compete with a test compound for binding the protein (see page 15, line 35 to page 16, line 2).

These utilities are not considered to be specific and substantial because the claimed polypeptide is not in hand, and because the specification fails to disclose any particular function or biological or biochemical significance for SEQ ID NO:6 protein of the instant invention. The polynucleotide encoding SEQ ID NO:6 appears to be of interest because analysis of electronic northern blotting profile (note that northern blotting is a type of *theoretical* analysis) shows that this polynucleotide is expressed in response to PAH exposure. From the expression of the polynucleotide encoding SEQ ID NO:6 polypeptide in response to PAH exposure, Appellants have concluded that the said polypeptide is useful for treating and preventing a disease associated with the altered gene expression in response to the PAH exposure, and useful for

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detecting a ligand specific binding to said polypeptide and purifying a ligand from sample. This polypeptide is not in-hand, and its amino acid sequence is deduced from the said polynucleotide sequence. Thus, once in-hand, after further research, specific and substantial credible utility might be found for the claimed isolated polypeptide compositions. The achievement of acquiring a polypeptide having SEQ ID NO:6 and determining its biological activity, however, is part of the act of invention.

The claimed protein is not supported by a specific asserted utility because the disclosed use of protein is generally applicable to screen a library of molecules, to purify a ligand from a sample (see page 4, the third paragraph); thus is not a particular component of the (pharmaceutical) composition set forth in the claims.

The claimed composition is not supported by substantial utility. The specification as filed does not disclose or provide any evidence that points to an activity (biological role or/and therapeutic role) of the protein because it is not in-hand. Also, it is not stated to show homolog with any known proteins to infer its activity. Use of the claimed protein for treating a disease requires knowing biological function of the said protein. Additionally, there is no art of record that discloses or suggests any activity for the claimed protein, and the specification does not infer any activity by homology comparison. Further, potential diagnostic and treatment utility of the claimed protein is not yet known and has not yet been disclosed in the specification. These asserted utilities constitute carrying further research upon the protein being in hand to identify or reasonably confirm "real world" context of use (e.g., diagnosing or/and treating a particular disease state). Thus, the test for substantial utility is not considered to be met.

The instant claims are drawn to a polypeptide (SEQ ID NO:6), which sequence is deduced from polynucleotide (SEQ ID NO:1) of as yet undetermined function or biological or biochemical significance. There is no evidence of record or any line of reasoning that would support a conclusion that the SEQ ID NO:6 protein of the instant application was, as of the filing date, useful for treating or preventing the disease (e.g., cancer) associated with the altered expression of a gene that is expressed in response to PAH in a subject *via* administering to said subject the

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pharmaceutical composition comprising the said polypeptide as stated at page 4 of the specification. Until some actual and specific significance can be attributed to the SEQ ID NO:6 polypeptide identified in the specification, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or “real world” utility as of the filing date.

**Written description/35 U.S.C § 112, first paragraph**

Claims 15-16 and 19 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Besides the protein of SEQ ID NO:6, the specification fails to provide any written description as to how to make any isolated immunogenic fragments of said protein and how to test for their immunogenicity. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The instant claim language “a immunogenic fragment” includes a large quantity of subsequences, i.e., variants (the number of the variants is estimated at least  $1.7 \times 10^5$ ). Such the recitation does not require that the corresponding polypeptide possesses the full-length sequence of SEQ ID NO:6 but rather encompasses any subsequences or have *per se* been. Thus one skilled in the art must determine for themselves which subsequences of SEQ ID NO:6 would be selected for uses, *e.g.*, raising antibodies, for diagnosing or treating a disease state.

It is known from the art records that the folded full-length protein is immunogenically different from the unfolded oligopeptide. Characteristics of the surface of a folded protein play an important role in antibody recognition. The amino acids may be widely separated in the linear structure of the protein but are close together when folded. The epitope recognition by an antibody is of two basic types: (1) linear epitope that represents unfolded linear oligopeptide or

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polypeptide, and (2) conformational epitopes in which the area recognized in the protein exists as a result of a 3-dimensional structure (*folded*) (see Miller, E. J. et al. *Am. J. Physiol.* (1991) 260, 1-12). Folding state and accessibility of antigen's idiotope to antibody are determining factors for affinity, specificity and valency with respect to antibody-antigen interaction. The specification is silent in providing guidance or/and working examples regarding whether or not the fragments refer to the said conformational epitopes. Given that conformational epitopes is important for immunogenicity, the specification does not teach how to make the fragments folded, or partially folded.

Because the fragment structure is variant and undetermined, use of the fragment polypeptide in purifying a ligand that specifically binds to the claimed polypeptide, drug screening and diagnosing and treating a disease state is unpredictable. All of the above-asserted uses require having the polypeptide fragment in hand, and knowing at least its peptide or protein structure or biological function. Yet, none of these have been disclosed in the specification.

Since the claimed polypeptide or fragment is not in hand, one skilled in the art cannot characterize its structure including folding state in order to produce the functional immunogenic fragment. Appellants are not in possession of the claimed invention. One skilled in the art would not know how to make and use the claimed invention so that it would operate as intended without undue experimentation.

Also, since toxic PAH induces apoptosis which is evidenced by the fact that the PAH acts on a transcription factor (AhR) and induces apoptosis (see Shafat, A. et al. (2000) *Mol. Pharmacol.* 58, 515-525), and since apoptosis, a programmed cell death, adds other unpredictability into the expression profiling of SEQ ID NO:6 or fragment thereof, the specification needs also to provide sufficient guidance to support the enablement. Therefore, absent the ability to predict how to reproducibly make said polypeptide or fragment thereof, and lack of data on particulars for activity, practicing the claimed invention would require a level of experimentation excessive and undue. Thus, the recitation of an immunogenic fragment, in the absence of any practical form of

the fragment in hand and its testable function, does not allow the skilled artisan to make and use the claimed composition without undue experimentation.

**(11) *Response to Argument***

**Issue 1: Utility rejection under 35 U.S.C. §101**

**I. The claimed invention has a well-established utility**

Appellants have cited many new references in their Appeal Brief to support the general knowledge of gene and protein expression profiling. These references have not risen to the level of officially making them of record because they have not been placed on a PTO 1449. This is of no consequence because the routine use of gene and protein expression profiling is not being questioned. Thus, the Examiner will only address Appellants arguments and not the references cited to support their arguments.

Also, Appellants continue to discuss the utility of the gene encoding the polypeptide having SEQ ID NO: 6. Application 09/386493 directed to the nucleic acid encoding SEQ ID NO: 6 has been allowed, because the nucleic acid has been asserted and shown to be useful in gene expression profiling. The elected claims of the instant application are drawn to the polypeptide comprising SEQ ID NO: 6 or immunogenic fragment thereof. Thus, only arguments that focus on this polypeptide or the fragment will be considered in this Examiner's Answer.

Since the current invention is directed to the polypeptide, only the asserted utilities of said polypeptide will be considered in this Office action. MPEP 2106 states: The applicant is in the best position to explain why an invention is believed useful. Office personnel should therefore focus their efforts on pointing out statements made in the specification that identify all practical applications for the invention. Office personnel should rely on such statements throughout the examination when assessing the invention for compliance with all statutory criteria. An applicant may assert more than one practical application, but only one is necessary to satisfy the utility

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requirement. Office personnel should review the entire disclosure to determine the features necessary to accomplish at least one asserted practical application.

Deficiencies under the “useful invention” requirement of 35 U.S.C. 101 will arise where it is not apparent why the invention is “useful” when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966); *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). The Supreme Court refused to consider sufficient a general assertion, not made in the application as filed but instead made by the applicant during an interference proceeding, that the compounds in question were structurally similar to others and therefore might possess a particular biological activity in common with those other compounds. Thus, the Court focused on the fact that the applicant failed to identify any *specific* utility for the claimed invention in his application. In this instant application, protein expression profiling is not an asserted specific and substantial utility found in the specification. Rather, the asserted utilities for the polypeptide having SEQ ID NO: 6 are:

- The protein can be used to screen a library of molecules or compounds to identify at least one ligand which specifically binds the protein (see page 4, the 3<sup>rd</sup> paragraph).
- The protein can be used to purify a ligand from a sample (see page 4, the 3<sup>rd</sup> paragraph).
- The protein can be used to treat or to prevent a disease associated with the altered expression of a gene that is expressed in response to PAH in a subject in need”; the said treatment or prevention “comprises administering to the subject in need the pharmaceutical composition containing the polypeptide in an amount effective for treating or preventing the disease” (see page 4, the 3<sup>rd</sup> paragraph).
- The disclosed polypeptide can be used for “the diagnosis of diseases characterized by the over-or-under expression of the disclosed protein” (see page 15, the last paragraph).
- The disclosed polypeptide can be used for drug screening assays in which neutralizing antibodies capable of binding the disclosed protein specifically compete with a test compound for binding the protein (see page 15, line 35 to page 16, line 2).

At pages 4-5 and 8-9, Appellants submit, based on the Furness declaration, that the claimed polypeptide can be used in protein expression analysis (expression profiling), e.g., 2-D PAGE gels and western blots in order for better assessing the potential toxic effect of a drug candidate (see page 4) and monitoring the drug efficacy and toxicity (pages 8-9). The Furness declaration discusses protein expression profiling in general, and is not specific to SEQ ID NO:6. At pages 5-6, Appellants submit that the law never has required knowledge of biological function to prove utility, and that expression analysis is useful in drug discovery and toxicology test. Further, at page 7, again Appellants submit that the use of the polypeptide in expression monitoring applications (e.g., toxicology testing) are independent of the precise function of the polypeptide. This has been fully considered but is not found to be persuasive for the following several reasons.

Appellants argue that the polypeptide having SEQ ID NO: 6 can be used in protein expression profiling. This utility is not set forth in the specification. Thus, the specification does not teach one skilled in the art to use the polypeptide having SEQ ID NO: 6 in protein expression profiling. Therefore, at the time the invention was made, Appellants did not recognize that the polypeptide having SEQ ID NO: 6 could be useful in protein expression profiling. Indeed, the polypeptide is not in hand and its sequence is deduced from the nucleic acid sequence having SEQ ID NO: 1. When one has not recombinantly produced the protein and obtained it in purified form, one would not have known how to use in protein expression profiling because one would not have known its 3-dimensional structure or the biochemical properties such as protein having SEQ ID NO:6 sequence and how it will migrate on a 2-D PAGE gel or run on western blot to be part of a protein expression profiling in response to the PAH exposure, for example.

In respect to Furness's Declaration of using the protein in drug discovery and toxicology testing, the specification does not teach any specific diseases which can be treated by a drug compound identified using the claimed polypeptide, the asserted utility is absent.

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At page 7, Appellants discuss US application No. 09/386493, i.e., Kaser' 493 (now US Pat. No. 6262247) in which the nucleic acid encoding SEQ ID NO:6 polypeptide has been allowed. Again, the nucleic acid is not under examination and will not be addressed in this Examiner Answer.

From page 5 to page 21, Appellants have also submitted the declarations of Rockett, Bedilion, and Iyer, in addition to Furness's Declaration, on the subjects of gene expression profiling. While these declarations and arguments are noted, these declarations and arguments discuss the polynucleotides and do not advance how one skilled in the art would use the polypeptide having SEQ ID NO:6 in expression profiling, or why one skilled in the art would glean from the specification that they should use this polypeptide having SEQ ID NO: 6 in protein expression profiling. Again, the expression profiling of SEQ ID NO:6 in response to PHA exposure is not taught in the specification.

## **II. The patent examiner's rejections are alleged as being without merit**

*A. The claimed polypeptide is alleged to have utility which is based on that membership in a class of useful products can be proof of utility*

At pages 22-25, Appellants state that the polypeptide has utility because it belongs to a general class of expressed polypeptides. Appellants discuss that membership in a "general" class is insufficient to determine utility only if the class contains a sufficient number of useless members such that a person of ordinary skill in the art cannot impute utility by a substantial likelihood. (see page 23, the 2<sup>nd</sup> paragraph). Appellants further infer that Examiner has not presented any evidence that the claimed polypeptide falls into those useless members; thus, Examiner must conclude that there is asserted utility associate with the claim polypeptide (see the 4<sup>th</sup> paragraph at page 23). This is found to be unpersuasive because of the following reasons.

- The polypeptide has not been expressed, or isolated. Thus, these arguments appear to be misguided. Without knowing these properties or/and functions, the skilled artisan and the

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Examiner cannot categorize the polypeptide into a particular family and compare it to the any members of any protein or enzyme families. Therefore, evaluating well-established utility of the claimed polypeptide cannot be based upon comparison and analysis of any members of known protein/enzyme families.

- For the asserted utilities for the polypeptide having SEQ ID NO: 6, e.g., treating a disease, one must know the function of the polypeptide. Yet, none is offered.
- Nowhere does the specification define or describe that the claimed polypeptide belongs to any protein or enzyme family.
- Appellants should have presented evidence as to usefulness of the claimed polypeptide in the instant disclosure but have not done so.
- The case law indicates that a rejection under 35 U.S.C. § 101 *for lack of operability* can be overcome by a showing of actual use or commercial success. The instant issue is whether or not the asserted utilities meet the three-pronged test for credibility, specificity, and substantiality. Such is not necessarily addressed by a showing of commercial success or actual use. Many products which lack patentable utility enjoy commercial success, are actually used, and are considered valuable.

Thus, Examiner concludes that there is no asserted utility associated with the current invention.

**B. *The precise biological role or function of an expressed polypeptide is alleged as being not required to demonstrate utility***

At the bottom of page 23, Appellant characterizes the examiner's rejection as being based on the grounds that, without information as to the precise biological role of the claimed invention, the claimed invention lacks specific patentable utility. Appellants argue that specific and substantial biological function may be required by technical journals, but are not necessary for patents, i.e., knowledge of biological function is not required in current invention. Appellants submit that the relevant question is not how or why the invention works, but rather whether the invention provides an "identifiable benefit" in presently available form, and that the present invention

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meets this test. This is found to be not persuasive. It mischaracterizes the examiner's position.

Rather, the specification does not teach how one would use the protein to

(i) to screen a library of molecules or compounds to identify at least one ligand which specifically binds the protein; (ii) to purify a ligand from a sample; (iii) to treat or to prevent a disease associated with the altered expression of a gene in response to PAH exposure in a subject, which treatment or prevention comprises administering to the subject the pharmaceutical composition containing the polypeptide in an amount effective for treating or preventing the disease; (iv) to diagnose diseases characterized by the over-or-under expression of the disclosed protein; and (v) to conduct drug screening assays.

*C. Alleged uses of SEQ ID NO:6 polypeptide in toxicology testing, drug discovery, and disease diagnosis are practical uses beyond mere study of the invention itself*

At pages 25-26, Appellants argue that use of the polypeptide as research tool is an acceptable utility. Appellants submit that the claimed invention has numerous other uses, each of which alone has a "substantial utility", e.g., in screening assay to identify specific ligands. This is not found to be persuasive for the following reasons.

- Indeed, it can be useful as a tool for research if one knows how to use it in research. At present, the claimed polypeptide is not available in practical form; thus, it cannot be useful in this regard. In addition, Appellants have failed to set forth how to use the polypeptide, even in protein expression profiling. It is for another to determine for themselves how to use it. This falls short of providing utility for the polypeptide having SEQ ID NO: 6.
- While a 2-D PAGE or Western blotting technique *per se* has patentable utility as a research tool, the subject protein is used in this "tool" has not been demonstrated, and thus, the claimed composition lacks utility.

*D. Appellant alleges that the Patent Examiner failed to demonstrate that a person of ordinary skill in the art would reasonably doubt the utility of the claimed invention*

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At pages 26-28, Appellants argue against the issue as to relation between the protein expression and mRNA expression. Appellants link the utility of the polynucleotide encoding the claimed polypeptide to utility of said polypeptide in order to demonstrate usefulness of the claimed invention. Again, here the appellants' argument is not within focus of this Examiner answer because, as stated above, only arguments referring to the claimed polypeptide will be considered in this Office action.

### **III. Applicants' allegation as to the patent examiner misstate the law.**

At pages 28-30, Appellants challenge the legality of the Patent Examination Utility Guidelines. The Examiner has no authority to comment on the legality of the Guidelines.

#### **Issue 2: The Enablement rejection under 35 U.S.C. § 112, first paragraph with regard to use of the claimed composition, e.g., in toxicology testing, drug development and diagnosis of disease**

At the bottom of pages 30-31, Appellants indicate that a rejection under § 112, first paragraph rejection is based on the improper allegation of lack of patentable utility under 35 USC § 101, it fails for the same reasons. See the Examiner comments regarding the above-mentioned utility.

#### **Issue 3: Written description Rejection under 35 U.S.C. § 112, first paragraph with regard to the claimed composition comprising the polypeptide of SEQ ID NO:6 or an immunogenic fragment thereof**

At pages 32-33, appellants contend that the claimed polypeptide of SEQ ID NO:6 and the immunogenic fragment thereof are sufficiently described for the skilled artisan to recognize that appellants are in possession of the them and to know how to use them without undue experimentation. Appellants submit that the specification has described the method of identifying suitable fragments for any particular protein (referring to specification at page 22-23 and

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Example VIII with respect to the software LASERGENE) and methods of how to make antibodies; and that the specification has set forth how to identify antigenic fragments (that are at least 15 amino acids in length) using the said software. Appellants conclude that there is no undue experimentation needed for one skilled in the art to prepare suitable immunogenic fragments for antibody production (see page 33, the 2<sup>nd</sup> paragraph). This is not persuasive for the several reasons:

- The Courts stated in *In re Gardner* (166 USPQ 138) that: the law requires that disclosure in an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. Here, in this case, using the software to find out how to use the claimed polypeptide fragment is not therefore protected by the law.
- Again, the polypeptide having SEQ ID NO:6 is not in hand; therefore, the production of the immunogenic fragment falls short of having written description.
- The claimed immunogenic fragment represents a genus that encompasses numerous variant peptide fragments. The specification fails to teach any of these. Appellant is thus not in possession of a genus (see MPEP 2163 II A.3 (a)(ii)).
- Because 3-D structure of the immunogenic polypeptide is a determinant of antigenicity (see Miller, E. J. et al. *Am. J. Physiol.* (1991) 260, 1-12), without the fragment in hand, the structure in no way can be characterized. Thus, the instant application is not enabling for claimed fragment and the composition comprising the fragment.
- The instant claims are drawn to a polypeptide (SEQ ID NO:6) of as yet uncharacterized function. There is no evidence of record or any line of reasoning that would support a conclusion that (i) the SEQ ID NO:6 protein or fragment thereof of the instant application was useful for treating or preventing the disease (e.g., cancer) associated with exposure to toxic PAH compound; and (ii) the composition comprising the said polypeptide and said fragment (see the instant claims 15 and 19) is useful for treating a disease state.
- Mediation (e.g., using the soft ware) of polypeptide function is insufficient for revealing utility of the polypeptide. In order to satisfy the enablement set forth by 35 USC 112, the first paragraph, the invention has to teach how to make and use the claimed composition.

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The software analysis is insufficient description of the current invention, it only identifies an approach for evaluating or helping search for potential region of immunogenicity. This is not adequately correlated to the claimed fragment (variant). Thus, use of the software *per se* to identify the immunogenic fragments does not sufficiently describe how to make and use the claimed compositions. Therefore, searching for the claimed immunogenic fragment of the protein requires constitute undue experimentation far beyond the software-assisted search.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




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March 28, 2004

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